UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

KARIM KHOJA, on behalf of himself and all others similarly situated,

Plaintiff,

v.

OREXIGEN THERAPEUTICS, INC., JOSEPH P. HAGAN, MICHAEL A. NARACHI, and PRESTON KLASSEN,

Defendants.

AND ALL CONSOLIDATED CASES

Case No.: 15-CV-540 JLS (JLB)

ORDER: (1) GRANTING IN PART DEFENDANTS' REQUEST FOR JUDICIAL NOTICE, (2) GRANTING DEFENDANTS' MOTION TO DISMISS, AND (3) DISMISSING LEAD PLAINTIFF'S CONSOLIDATED COMPLAINT

(ECF No. 62)

Presently before the Court is Defendants Orexigen Therapeutics, Inc., Joseph P. Hagan, Michael A. Narachi, and Preston Klassen's Motion to Dismiss Consolidated Complaint for Violation of the Federal Securities Laws. (MTD, ECF No. 62.) Also before the Court are Lead Plaintiff Karim Khoja's Opposition to (ECF No. 67) and Defendants' Reply in Support of (ECF No. 69) the MTD, as well as Defendants' Request for Judicial Notice (ECF No. 62-25) and Lead Plaintiff's Objections to (ECF No. 68) and Defendants'

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Reply in Support of (ECF No. 69-1) the RJN.[1] The Court vacated the hearing and took the matter under submission without oral argument pursuant to Civil Local Rule 7.1(d)(1). (ECF No. 70.) Having considered the parties' arguments and the law, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' RJN (ECF No. 62-25), **GRANTS** Defendants' MTD (ECF No. 62), and **DISMISSES** Lead Plaintiff's Consolidated Complaint (CC, ECF No. 55).

BACKGROUND

I. Factual Background

Defendant Orexigen is a developmental stage biotechnology firm focusing on the development of pharmaceutical product candidates for the treatment of obesity. (Consolidated Compl. (CC) ¶ 7, ECF No. 55.) Defendant Orexigen is a small company with approximately fifty employees. (*Id.* at ¶ 33.) Its common stock is traded on the NASDAQ. (*Id.* at ¶¶ 33, 131(a).) Defendant Narachi is Defendant Orexigen's CEO and a director. (*Id.* at ¶ 34.) Defendant Hagan is the Chief Business Officer and Acting CFO of Defendant Orexigen (*id.* at ¶ 36), while Defendant Klassen is its Head of Global Development (together with Defendant Narachi, the Insider Defendants) (*id.* at ¶ 38).

Defendant Orexigen's primary obesity treatment candidate is Contrave (*id.* at ¶ 7), which is designed to treat overweight and obese persons already at high risk for major adverse cardiovascular events (MACE), defined as myocardial infarction (heart attack), stroke, or cardiovascular death (*id.* at ¶¶ 8, 87). Contrave is made from two off-patent generic drugs, bupropion and naltrexone. (*Id.* at ¶ 66.) Defendant Orexigen has a collaboration agreement with Takeda Pharmaceutical Company Limited to develop and commercialize Contrave in the United States, Canada, and Mexico. (*Id.* at ¶ 7.)

Defendant Orexigen submitted a new drug application for Contrave to the United States Food and Drug Administration (FDA). (*Id.* at ¶ 49.) Concerned that Contrave may

[1] Lead Plaintiff has also filed a number of notices of supplemental materials (*see* ECF Nos. 71, 72, 74), to which Defendants have responded (*see* ECF Nos. 73, 75).

cause adverse cardiovascular events because of its effect on blood pressure and heart rate (*id.* at ¶ 127), in January 2011 the FDA mandated a randomized, double-blind, placebo-controlled clinical trial designed to assess the cardiovascular risks associated with Contrave (the Light Study) before the new drug application could be approved (*id.* at ¶¶ 8, 49). The Light Study's Executive Steering Committee was chaired by Dr. Steven Nissen, a Department Chair of Cardiovascular Medicine at the Cleveland Clinic. (*Id.* at 5 n.1.[2]) Defendant Orexigen initiated the Light Study in June 2012 and completed screening in December 2012, resulting in approximately 8,900 patients randomized for treatment. (*Id.* at ¶ 51.) The FDA agreed that if the Light Study's interim analysis revealed that Contrave did not increase the risk of a major cardiac event by 50% or more, Contrave could be approved. (*Id.* at ¶¶ 51, 96, 126.)

In November 2013, the Light Study's Data Monitoring Committee shared with Defendant Orexigen the completed interim results. (*Id.* at ¶ 52.) The results, based on ninety-four MACE, which was approximately 25% of the planned MACE for the Light Study, indicated that Contrave reduced cardiovascular events by 41% compared with a placebo. (*Id.* at ¶¶ 70, 87.) Specifically, thirty-five Contrave patients experienced MACE, while fifty-nine placebo patients did. (*Id.* at ¶ 88.)

The Light Study's steering committee, Data Monitoring Committee, and Defendant Orexigen entered into a data access plan, in which they agreed to limit the number of people within Defendant Orexigen who had access to the interim results to just those individuals who needed to facilitate submission of Defendant Orexigen's marketing application to the FDA. (*Id.* at ¶ 53 & n.10.) The Light Study's statistical review team, however, subsequently discovered that Defendant Orexigen had leaked the positive interim data to over 100 people. (*Id.* at ¶¶ 10, 53.) Included among those to whom the data was leaked was Defendant Narachi, who publicly pledged in a November 25, 2013 *Forbes* article, "We're going to honor the integrity of [the Light Study's] blind so we don't screw it up

[2] Pin citations to docketed materials refer to the CM/ECF page number stamped at the top of the page.

and get the final analysis." (*Id.* at ¶¶ 9, 52, 58.) Others who saw the data included investment bankers and several representatives from Takeda. (*Id.* at ¶ 58.) The FDA later confirmed in a September 10, 2014 report that Defendant Orexigen had improperly disseminated unblinded interim data "far beyond the intended core group." (*Id.* at ¶ 58 (emphasis omitted).) The Light Study's Data Monitoring Committee "found that it [was] particularly concerning that members of Orexigen's Board of Directors . . . , who have financial interest in the outcome of the trial, were also provided full access to the unblinded data." (*Id.* (emphasis omitted).) On February 3, 2014, Defendant Orexigen submitted a second data access plan to the FDA. (*Id.* at ¶¶ 11, 60; *see also* RJN Ex. A at 9, ECF No. 62-3.)

At a June 4, 2014 meeting, the FDA reminded Defendants Narachi and Klassen that the 25% interim results have "a high degree of uncertainty and were likely to change with the accumulation of additional data." (CC ¶ 59, ECF No. 55.) The FDA was also concerned that Defendant Orexigen's corporate leaders knew the 25% interim results. (*Id.* at ¶ 10.) The FDA also noted that the unblinding violated Defendant Orexigen's data access plan and that the extent of the confidentiality breach of interim results in the Light Study was unprecedented. (*Id.*)

On July 2, 2014, Defendant Orexigen filed patent application mi,ber 14/322,810 (the '810 Application) with the United States Patent and Trademark Office (USPTO), listing Defendant Klassen as the "patent applicant" and "inventor." (*Id.* at ¶¶ 12, 61.) The '810 Application covered a new indication—a cardiovascular benefit—for Contrave based on the 25% interim data. (*Id.* at ¶ 66.) The '810 Application explicitly included the 25% interim Light Study data (*id.* at ¶¶ 12, 62), and noted:

> Surprisingly, rather than increasing the occurrence of MACE in this high risk patient population, the results indicate that treatment with [Contrave] decreases the occurrence of MACE in overweight and obese subjects with cardiovascular risk factors. Briefly stated, fewer subjects in the [Contrave] treatment group experienced a MACE even compared to placebo.

(*Id.* at ¶ 62 (alterations in original) (emphasis omitted).) Pursuant to 35 U.S.C. § 122,

Defendant Orexigen requested that the USPTO keep the '810 Application confidential. (*Id.* at ¶¶ 12 & n.6, 61.) As part of that request, Defendant Orexigen had to "certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing." (RJN Ex. H at 3, ECF No. 62-10 (emphasis in original).) Defendant Orexigen also requested prioritized examination of the '810 Application pursuant to 37 C.F.R. § 1.102(e). (*Id.* at 9–10.)

On September 10, 2014, the FDA approved Contrave for commercial use (CC ¶¶ 14, 55, 126, ECF No. 55), and on November 26, 2014, the USPTO allowed the '810 Application for issuance as a patent (RJN Ex. H at 11–19, ECF No. 62-10). The USPTO's letter indicated that the issuance fee for the '810 Application had to be paid by February 26, 2015. (*Id.* at 11.)

In December 2014, the Committee for Medicinal Products for Human Use (CHMP), the centralized expert advisory committee of the European Medicines Agency, adopted a positive opinion for Contrave[3] and recommended that the European Commission grant a centralized marketing authorization. (CC ¶ 63, ECF No. 55.) The European Commission also informed Defendant Orexigen that it would review a draft decision granting marketing authorization for Contrave during a meeting of the Standing Committee scheduled for March 2015. (*Id.*)

On December 4, 2014, Defendant Orexigen filed patent application number PCT/US2014/068527 with the World Intellectual Property Organization (the WIPO Application). (RJN Ex. V, ECF No. 62-24.) The WIPO Application incorporated by reference the '810 Application. (*Id.* at 3.) On January 5, 2015, Defendant Orexigen sent the USPTO a Rescission of Previous Nonpublication Request, of which the USPTO acknowledged receipt on January 12, 2015. (CC ¶¶ 14, 64, ECF No. 55; *see also* RJN Ex. H at 20–21, 23, ECF No. 62-10.) The rescission noted that "[i]f a notice of foreign or

[3] Contrave is marketed under the name Mysimba in Europe. (*Id.* at ¶ 63 n.16.)

international filing is or will be required by 35 U.S.C. 122(b)(2)(B)(iii) and 37 CFR 1.213(c), I hereby provide such notice." (RJN Ex. H at 20, ECF No. 62-10.) The USPTO informed Defendant Orexigen that "the earliest possible projected publication date" was June 11, 2015. (*Id.* at 23.) Defendant Orexigen paid the issue fee for the '810 Application on January 20, 2015. (*Id.* at 24.)

On February 5, 2015, Defendants Hagan and Narachi were awarded a stock option grant on 202,605 and 635,150 shares, respectively, at an exercise price of $5.34 (CC ¶ 84, ECF No. 55), and on February 11, 2015, the USPTO advised Orexigen that the '810 Application would be issued as a patent on March 3, 2015 (*id.* at ¶ 67).

On February 25, 2015, Defendant Klassen informed investors on a conference call that "there won't be any release of the [Light Study] information unless pre-specified boundaries are hit." (*Id.* at ¶ 67 (emphasis omitted).) Defendant Orexigen's February 27, 2015 10-K noted that "[d]isclosure of interim results of ongoing clinical trials, including disclosure of interim results related to the protection of intellectual property . . . could significantly affect our product development costs or adversely impact our ability to maintain or receive additional regulatory approvals." (*Id.* at ¶ 68 (alteration in original) (emphasis omitted).)

On March 3, 2015, the USPTO issued U.S. Patent No. 8,969,371 (the '371 Patent) from the '810 Application. (RJN Ex. G, ECF No. 62-9; *see also* CC ¶¶ 15, 69, ECF No. 55.) Defendant Orexigen also filed an 8-K announcing the publication of '371 Patent and releasing the 25% interim Light Study Results. (CC ¶¶ 15, 69, 87, ECF No. 55.) The 8-K noted that the '371 Patent "incorporate[d] data from [the Light Study]," and that the '371 Patent "contain[s] claims related to a positive effect of Contrave on CV outcomes" based on an "analysis . . . conducted based on 94 observed an adjudicated [MACE], which was approximately 25% of the planned MACE for the Light Study." (*Id.* at ¶ 87.) The 8-K further explained that the interim analysis "was prospectively designed to enable an early and preliminary assessment of safety to support regulatory approval" and that "[a] larger number of MACE are required to precisely determine the effect of Contrave on CV

outcomes." (*Id.*) It also stressed that, "**[i]mportantly, the U.S. package insert for Contrave states that the effect of Contrave on CV morbidity and mortality has not been established.**" (RJN Ex. J at 3 (emphasis in original), 5, ECF No. 52-12.) The 8-K also disclosed that "[a] second, large, randomized, placebo-controlled clinical trial evaluating the effect of Contrave on CV outcomes is planned to start later this year." (*Id.* at 5.) Defendant Orexigen did not consult the FDA, Dr. Nissen, or Takeda prior to filing the 8-K. (CC ¶ 15, ECF No. 55.)

Forbes reported that FDA senior official Dr. John Jenkins had stated that the FDA was unaware that Defendant Orexigen's '810 Application contained the 25% interim data and expressed "serious concerns" about Defendant Orexigen's disclosure of the interim data. (*Id.* at ¶¶ 93, 118.) The FDA reported that it was "very disappointed by Orexigen's actions" and warned patients and physicians that it was "critical that the[] interim data [] not be misinterpreted." (*Id.* at ¶ 93 (alterations in original).) The FDA noted that endpoints with less than 100 total events are statistically unreliable and were to be viewed with extreme caution. (*Id.* at ¶ 118.)

Defendant Orexigen then published a March 3, 2015 press release, explaining that it "filed patent applications based on the results in order to preserve the potential for additional intellectual property." (*Id.* at ¶¶ 94, 119.) It also explained that "[d]uring the course of the study, the FDA informed [Defendant Orexigen] it had determined that the Light Study would not serve as the postmarketing requirement for Contrave; a new trial would be required." (*Id.* at ¶ 94) The new trial would start "later this year," and results "are anticipated by 2022." (*Id.*) "This morning the USPTO published the patent and supporting documentation, and [Defendant Orexigen] believed it was appropriate and necessary to make sure this information was equally available to all investors." (*Id.* at ¶¶ 94 (emphasis omitted), 119.) Although Defendant Orexigen's stock had closed at $5.79 per share on March 2, 2015, it closed on March 3, 2015 at $7.64 per share, trading as high as $9.37 per share. (*Id.* at ¶¶ 16, 89, 117.) More than 95.8 million of Defendant Orexigen's shares were traded on March 3, 2015, a "highly unusual trading volume" (*id.* at ¶¶ 89, 117),

especially when compared to the average daily trading volume of approximately 3 million shares per day (*id.* at ¶ 16 n.7).

Analysts responded positively to the 8-K. (*Id.* at ¶¶ 90–91.) Analyst Simos Simeonidis from RBC Capital Markets noted that "[w]e view the news as very significant" and "[t]he newly revealed data demonstrated that not only is Contrave safe to use from a CV standpoint, but it actually appears to have a CV benefit." (*Id.* at ¶ 90 (emphasis omitted).) Consequently, he rated Defendant Orexigen's shares to "outperform." (*Id.*) Analysts at Piper Jaffray noted that the Light Study's interim results "[c]ould turn the obesity/metabolic syndrome market on its head. We see this CVOT effect as surprisingly positive and it has several implications, in our view for the potential of Contrave." (*Id.* at ¶¶ 17, 90.) Leerink analyst Paul Matteis reported that "[t]he data this morning show a statistically significant Contrave benefit." (*Id.* at ¶ 91 (emphasis omitted).) Wells Fargo analyst Matthew J. Andrews, in analyzing the data, noted that "the 'holy grail' for treating cardiometabolic diseases is demonstration of a CV mortality benefit, which to date has not been demonstrated by an obesity therapeutic." (*Id.* at ¶¶ 17, 91 (emphasis omitted).)

On March 4, 2014, the *Wall Street Journal* published an article explaining that the FDA "considers the preliminary data 'far too unreliable to conclude anything further about cardiovascular safety.'" (*Id.* at ¶ 96 (emphasis omitted).) The article noted that "LIGHT study data was disclosed inappropriately" previously, and that the FDA had consequently decided that Defendant "Orexigen would have to launch a new study to satisfy the conditions of the approval of its Contrave drug." (*Id.*) The *Wall Street Journal* reported that Dr. Nissen, "the lead researcher for the study[,] is upset." (*Id.*) Dr. Nissen noted that "he was not aware of the interim study results until yesterday," "the disclosure was not approved by the data monitoring committee or the trial's executive committee," and Defendant Orexigen's business management was not included in the list of individuals with approved access to the data. (*Id.* (emphasis omitted).) On March 4, 2015, the price of Defendant Orexigen's stock closed at $8.49 per share (*id.* at ¶¶16, 97, 120), "again on unusually high trading volume of more than 40.5 million shares" (*id.* at ¶¶ 97, 120).

A March 5, 2015 *Forbes* article reported that "[t]here is widespread speculation that Orexigen used the excuse of the patent filing to publicly reveal the interim results of the trial." (*Id.* at ¶ 70 (emphasis omitted).) The *Forbes* article further reported that critics believed that "[d]isclosing the results, through the medium of a patent filing and an SEC disclosure, is a deeply cynical and manipulative action." (*Id.* (emphasis omitted).) *Forbes* also speculated that Defendant Orexigen's repeated disclosure of the Light Study interim results could potentially threaten its relationship with the FDA and its ability to obtain further drug approvals. (*Id.* at ¶ 121.) On March 5, 2015, Defendant Orexigen's stock closed at $8.01 per share, down from its opening price of $8.50 per share. (*Id.* at ¶¶ 19, 121)

After the close of trading on March 5, 2015, *Forbes* published another report, which included criticisms of Defendant Orexigen and its decision to release the interim trial data by Dr. Jenkins, the FDA's director of the Office of New Drugs. (*Id.* at ¶¶ 18, 122.) Dr. Jenkins criticized the released data as "unreliable," "misleading," and "likely false," and warned that Defendant Orexigen "could face fines, civil penalties, or even the withdrawal of Contrave from the market" if it did not complete the new post-marketing study that the FDA would require. (*Id.*; *see also* RJN Ex. C at 4, ECF No. 62-5) On March 6, 2015, the price of Defendant Orexigen's stock dropped to $6.76 per share in intraday trading and closed at $7.10 per share, "again on unusually high trading volume." (CC ¶¶ 19, 123, 125, ECF No. 55.)

On March 13, 2015, Defendant Orexigen filed a Form S-8 Registration Statement, registering six million shares of common stock at a proposed maximum offering price of $7.08 per share. (*Id.* at ¶¶ 20, 85; *see also* RJN Ex. T at 3, ECF No. 62-22.) In its March 26, 2015 Form 8-K, Defendant Orexigen announced that Contrave had received marketing authorization in Europe. (CC ¶¶ 21, 72, 99, ECF No. 55.) Over nine million shares of Defendant Orexigen's stock traded on that day, with stock prices increasing from an opening price of $6.89 on March 26, 2015 to a closing price of $7.54 on March 27, 2015. (*Id.*)

Also on March 26, 2015, Light Study researchers discovered that Contrave's purported 25% interim heart benefit vanished once the additional 50% Light Study results were considered. (*Id.* at ¶¶ 21, 74.) The Light Study's Executive Steering Committee unanimously voted to recommend stopping the Light Study and to immediately release the 50% interim data. (*Id.* at ¶¶ 74, 127) Defendants were shown the 50% interim data demonstrating that the 25% interim cardiovascular benefit had disappeared. (*Id.* at ¶¶ 21, 74, 99, 127.) Dr. Nissen began to draft a press release disclosing the 50% Light Study data and termination of the Light Study, which Takeda approved but Defendant Orexigen refused to authorize. (*Id.* at ¶¶ 21, 75.)

On May 8, 2015, Defendant Orexigen filed an 8-K containing a press release announcing its business and financial results for the first quarter ended March 31, 2015. (*Id.* at ¶ 100.) The press release noted that Contrave's "clinical trial program also includes a double-blind, placebo-controlled cardiovascular outcomes trial known as the Light Study." (*Id.* (emphasis omitted).) Defendant Orexigen also filed a 10-Q (*id.* at ¶ 103), noting that Defendant Orexigen's share price might be impacted by "announcements regarding [its] clinical trials, including [ ] the Light Study and the post-marketing required clinical trials, including the new CVOT, for Contrave" (*id.* at ¶ 104 (second alteration in original)). The 10-Q also represented that "additional analysis of the interim results or new data from the continuing Light Study, including safety-related data, and the additional cardiovascular outcomes trial, may produce negative or inconclusive results, or may be inconsistent with the conclusion that the interim analysis was successful." (*Id.* (emphasis omitted).) The 10-Q also noted that "[a]ny failure by [Defendant Orexigen] or delay in completing [its] clinical trials, including the Light Study, or in obtaining regulatory approvals, could cause a delay in the commencement of product revenues and cause [Defendant Orexigen's] research and development expenses to increase." (*Id.* at ¶ 105.)

Defendant also hosted an earnings conference call for analysts and investors on May 8, 2015. (*Id.* at ¶¶ 22, 107.) In response to a question about whether the Light Study had been terminated, Defendant Klassen represented that the "Light Study is continuing and

we are continuing to engage both Orexigen and Takeda with the FDA and with [Executive Steering Committee] and [Data Monitoring Committee] regarding ultimately the status of the study, but it's an ongoing entity as of right now." (*Id.* at ¶ 108 (emphasis omitted).) In response to a query about the 50% interim data, Defendant Klassen responded:

> We have passed the 50% time point and as we've stated before, those results are viewed by the Data Monitoring Committee and it wasn't a planned look by the sponsors, like the 25% was. The 25% was special because it was for regulatory purposes and so we have had 50% time point.

(*Id.* at ¶ 109 (alteration in original).) Defendant Narachi added:

> The results from the 50% analysis . . . only come out in the context of wrapping up the trial or as a final analysis. So, if the decision is made to terminate the trial early and focus resources on the next CVOT, which is what we have been advocating, then I think results would come out sooner.

(*Id.* (emphasis omitted).) Defendant Narachi also noted that "if there was a decision to terminate the [Light Study] . . . , that would be a disclosure that we would make." (*Id.* at ¶ 111 (emphasis omitted).)

On May 12, 2015, Defendant Orexigen and Takeda announced discontinuation of the Light Study (*id.* at ¶¶ 24, 126), but did not reveal the 50% data (*id.* at ¶¶ 24, 127). They noted that they were "pleased that the Light Study is now being terminated and want[ed] to thank the patients and all those involved in the study." (*Id.* at ¶ 27 (alteration in original) (emphasis omitted).) Minutes later, Dr. Nissen and the Cleveland Clinic issued a press release announcing both the termination of the Light Study and the 50% interim data. (*Id.* at ¶¶ 24, 75, 126, 127.) The 50% Light Study data revealed that at 192 MACE, the difference between the Contrave and placebo groups shrank to 12% and was no longer statistically significant. (*Id.* at ¶ 127.) Dr. Nissen noted:

> These results do not confirm the cardiovascular benefits of Contrave claimed by [Defendant] Orexigen in the patent application based on the data obtained at the 25 percent time point in the trial . . . . These results show neither benefit nor harm for patients taking the drug, but are consistent with the requirement by the FDA that the Light Trial demonstrate an absence of a doubling of cardiovascular risk for patients taking the drug . . . . The inconsistency of effects on cardiovascular outcomes between the first 25 percent and the

> second 25 percent of the Light Study clearly illustrates the risks inherent in pre-judgment of clinical trial results based upon an interim analysis and demonstrate why interim results should remain confidential during any ongoing trial.

(*Id.* at ¶ 126 (emphasis omitted).)

In an article appearing on *Forbes.com*, Dr. Nissen claimed that "[p]atients were misled, investors were misled." (*Id.* at ¶ 127 (emphasis omitted); *see also id.* at ¶ 25.) Dr. Nissen also noted that Defendant Orexigen had refused to approve a press release publicizing the 50% Light Study data for six weeks. (*Id.* at ¶¶ 25, 127.) An article published in *Medscape* on that same day quoted Dr. Nissen as saying:

> Essentially, when they [Orexigen] filed the patent the company chose what they were going to put in there and what they were going to leave out . . . . We felt it was in the public interest to take an unprecedented step and release the 50% data because we couldn't allow unreliable data to be used in clinical decision making. We had a duty to the public and also to the investment community, to tell the truth.

(*Id.* at ¶ 128 (alteration in original); *see also id.* at ¶ 26.) The price of Defendant Orexigen's common stock fell from an opening price of $6.75 on May 11, 2015, to $5.02 per share at the close of May 13, 2015. (*Id.* at ¶¶ 26, 130.)

II. Procedural Background

On March 10, 2015, Plaintiff Lisa Colley filed a class action complaint against Defendants, alleging (1) violation of § 10(b) of the 1934 Act and Rule 10b-5, and (2) violation of § 20(a) of the 1934 Act. (ECF No. 1.) The case was originally assigned to Judge M. James Lorenz. (*See id.*) Two related actions—*Stefanko v. Orexigen Therapeutics, Inc.*, No. 3:15-cv-00549-JAH-JLB, and *Yantz v. Orexigen Therapeutics, Inc.*, No. 3:15-cv-557-CAB-MDD—were filed on March 11, 2015. (ECF No. 4.)

On May 12 and 13, 2015, a number of competing motions for consolidation, appointment of lead plaintiff, and approval of lead counsel were filed. (*See* ECF Nos. 26, 27, 28, 29, 32, 33, 34, 35, 37, 38.) On June 15, 2015, Lead Plaintiff informed Judge Lorenz that his motions were unopposed. (ECF No. 42.) Consequently, Judge Lorenz granted

Lead Plaintiff's motions on June 22, 2015. (ECF No. 43.)

On June 26, 2015, Judge Lorenz recused himself from this action, which was reassigned to this Court. (ECF No. 46.) Lead Plaintiff filed its CC on August 20, 2015, and Defendants filed the instant MTD on October 5, 2015 (ECF No. 62).

DEFENDANTS' RJN

I. Legal Standard

Federal Rule of Evidence 201(b) provides that "[t]he court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." "Judicially noticed facts often consist of matters of public record." *Botelho v. U.S. Bank, N.A.*, 692 F. Supp. 2d 1174, 1178 (N.D. Cal. 2010) (citation omitted); *see also Reyn's Pasta Bella, LLC v. Visa USA, Inc.*, 442 F.3d 741, 746 n.6 (9th Cir. 2006) (The court "may take judicial notice of court filings and other matters of public record."). While "[a] court may take judicial notice of the existence of matters of public record, such as a prior order or decision," it should not take notice of "the truth of the facts cited therein." *Marsh v. San Diego Cnty.*, 432 F. Supp. 2d 1035, 1043 (S.D. Cal. 2006).

"When ruling on a Rule 12(b)(6) motion to dismiss, if a district court considers evidence outside the pleadings, it must normally convert the 12(b)(6) motion into a Rule 56 motion for summary judgment, and it must give the nonmoving party an opportunity to respond." *United States v. Ritchie*, 342 F.3d 903, 907–08 (9th Cir. 2003) (citing Fed. R. Civ. P. 12(b); *Parrino v. FHP, Inc.*, 146 F.3d 699, 706 n.4 (9th Cir. 1998)). "A court may, however, consider certain materials—documents attached to the complaint, documents incorporated by reference in the complaint, or matters of judicial notice—without converting the motion to dismiss into a motion for summary judgment." *Id.* at 908 (citing *Van Buskirk v. CNN*, 284 F.3d 977, 980 (9th Cir. 2002); *Barron v. Reich*, 13 F.3d 1370, 1377 (9th Cir. 1994); 2 James Wm. Moore et al., *Moore's Federal Practice* § 12.34[2] (3d ed. 1999)). "Even if a document is not attached to a complaint, it may be incorporated by

reference into a complaint if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *Id.* (citing *Van Buskirk*, 284 F.3d at 980; *Branch v. Tunnell*, 14 F.3d 449, 453–54 (9th Cir. 1994), *overruled on other grounds by Galbraith v. Cnty. of Santa Clara*, 307 F.3d 1119 (9th Cir. 2002); *Venture Assoc. Corp. v. Zenith Data Sys. Corp.*, 987 F.2d 429, 431(7th Cir. 1993)). "The defendant may offer such a document, and the district court may treat such a document as part of the complaint, and thus may assume that its contents are true for purposes of a motion to dismiss under Rule 12(b)(6)." *Id.*; *see also Marder v. Lopez*, 450 F.3d 445, 448 (9th Cir. 2006) ("The court may treat . . . a document [incorporated by reference] as 'part of the complaint, and thus may assume that its contents are true for purposes of a motion to dismiss under Rule 12(b)(6).'") (citing *Ritchie*, 342 F.3d at 908).

II. Analysis

Defendants ask the Court to take judicial notice of pursuant to Federal Rule of Evidence 201 and/or consider pursuant to the incorporation by reference doctrine twenty-two documents:

(1) Center for Drug Evaluation & Research, U.S. Food & Drug Admin., Summary Review for Regulatory Action for Application No. 200063Orig1s000 (Sept. 10, 2014), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/200063Orig1s000SumR.pdf (RJN Ex. A, ECF No. 62-3);

(2) Orexigen Therapeutics, Inc., Annual Report (Form 10-K) (Feb. 27, 2015) (RJN Ex. B, ECF No. 62-4);

(3) Ed Silverman, *Orexigen Data is 'Unreliable and Premature:' FDA's Jenkins Explains*, Wall St. J. (Mar. 6, 2015, 9:39 AM), http://blogs.wsj.com/pharmalot/2015/03/06/orexigen-data-is-unreliable-and-premature-fdas-jenkins-explains/ (RJN Ex. C, ECF No. 62-5);

(4) Orexigen Therapeutics, Inc., Current Report (Form 8-K) Ex. 99.1 (Sept. 11, 2014) (RJN Ex. D, ECF No. 62-6);

(5) Comm. for Medicinal Prods. for Human Use, European Med. Agency, Assessment Report for an Initial Marketing Authorisation Application for Mysimba (Dec. 18, 2014), *available at* http://www.ema.europa.eu/docs/en_

GB/document_library/EPAR_-_Public_assessment_report/human/003687/WC500185582.pdf (RJN Ex. E, ECF No. 62-7);

(6) Press Release, Comm. for Medicinal Prods. for Human Use, European Med. Agency, Mysimba Recommended for Approval in Weight Management in Adults (Dec. 19, 2014), *available at* http://ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/12/news_detail_002240.jsp&mid=WC0b01ac058004d5c1 (RJN Ex. F, ECF No. 62-8);

(7) U.S. Patent No. 8,969,371 (filed July 2, 2014) (RJN Ex. G, ECF No. 62-9);

(8) Excerpts from the USPTO's file history of the '371 Patent, including:

(a) U.S. Patent No. 8,969,371 Application Data Sheet (July 2, 2014) (RJN Ex. H at 2–8, ECF No. 62-10),

(b) Certification and Request for Prioritized Examination under 37 CFR 1.102(e) (July 2, 2014) (RJN Ex. H at 9–10, ECF No. 62-10),

(c) Notice of Allowance and Fee(s) Due (Nov. 26, 2014) (RJN Ex. H at 11–19, ECF No. 62-10),

(d) Rescission of Previous Nonpublication Request (Jan. 5, 2015) (RJN Ex. H at 20–21, ECF No. 62-10),

(e) Notice of New or Revised Projected Publication Date (Jan. 8, 2015) (RJN Ex. H at 22, ECF No. 62-10),

(f) Communication Regarding Rescission of Nonpublication Request and/or Notice of Foreign Filing (Jan. 12, 2015) (RJN Ex. H at 23, ECF No. 62-10), and

(g) Fee(s) Transmittal (Jan. 20, 2015) (RJN Ex. H at 24, ECF No. 62-10);

(9) Ed Silverman, *Fat Chance: FDA Chastises Orexigen for Disclosing Interim Trial Data*, Wall St. J. (Mar. 4, 2015, 10:57 AM), http://blogs.wsj.com/pharmalot/2015/03/04/fat-chance-fda-chastises-orexigen-for-disclosing-interim-trial-data/ (RJN Ex. I, ECF No. 62-11);

(10) Orexigen Therapeutics, Inc., Current Report (Form 8-K) (Mar. 3, 2015) (RJN Ex. J, ECF No. 62-12);

(11) Simos Simeonidis, RBC Capital Markets, *Orexigen Therapeutics Inc: LIGHT Interim Data Reveal Contrave Positive CV Effect; Extend IP by 7 Years*, Equity Research: First Glance (Mar. 3, 2015) (RJN Ex. K, ECF No. 62-13);

(12) Paul Matteis & Jason M. Gerberry, Leerink Partners LLC, *Orexigen Therapeutics, Inc.: 25% Interim LIGHT Analysis Shows Stat. Sig Contrave*

Benefit on CV Outcomes (Mar. 3, 2015) (RJN Ex. L, ECF No. 62-14);

(13) Adam Feuerstein, *Orexigen Weight-Loss Pill Shows Surprise Heart-Safety Benefit*, www.thestreet.com (Mar. 3, 2015, 11:51 AM), *available at* http://www.thestreet.com/story/13065624/1/orexigen-weight-loss-pill-shows-surprise-heart-safety-benefit.html (RJN Ex. M, ECF No. 62-15);

(14) Matt Herper, *The FDA Is Forcing Orexigen to Do a Second Safety Study Because of Contrave Disclosures*, www.forbes.com (Mar. 3, 2015, 3:33 PM), *available at* http://www.forbes.com/sites/matthewherper/2015/03/03/the-fda-will-force-orexigen-to-do-a-second-safety-study-because-of-contrave-disclosures/ (RJN Ex. N, ECF No. 62-16);

(15) Matt Herper, *Top FDA Official Says Orexigen Study Result 'Unreliable,' 'Misleading,'* www.forbes.com (Mar. 5, 2015, 5:28 PM), *available at* http://www.forbes.com/sites/matthewherper/2015/03/05/top-fda-official-says-orexigen-data-unreliable-likely-false/ (RJN Ex. O, ECF No. 62-17);

(16) Paul Matteis & Jason M. Gerberry, Leerink Partners LLC, *Orexigen Therapeutics, Inc.: Meeting with Mgmt Highlights Partnering Goals, Next Steps for CV Studies* (Apr. 6, 2015) (RJN Ex. P, ECF No. 62-18);

(17) Press Release, Orexigen Therapeutics, Inc., Takeda Pharmaceuticals and Orexigen Therapeutics Announce Termination of the Cardiovascular Outcomes Study (Light Study) of the Obesity Drug Contrave (naltrexone HCl and bupropion HCl) (May 12, 2015), *available at* http://ir.orexigen.com/phoenix.zhtml?c=207034&p=irol-newsArticle&ID=2046959 (RJN Ex. Q, ECF No. 62-19);

(18) Orexigen Therapeutics, Inc., Proxy Statement (Schedule DEF-14A) (Apr. 30, 2014) (RJN Ex. R, ECF No. 62-20);

(19) Orexigen Therapeutics, Inc., Proxy Statement (Schedule DEF-14A) (Apr. 30, 2014) (RJN Ex. S, ECF No. 62-21);

(20) Orexigen Therapeutics, Inc., Registration Statement (Form S-8) (Mar. 16, 2015) (RJN Ex. T, ECF No. 62-22);

(21) Orexigen Therapeutics, Inc., Proxy Statement (Schedule DEF-14A) App. A (RJN Ex. U, ECF No. 62-23); and

(22) World Intellectual Property Organization Patent Application No. WO/2015/085044 (filed Dec. 4, 2014) (RJN Ex. V, ECF No. 62-24).

Defendants argue that "[a]ll of these documents are appropriate for judicial notice under Federal Rule of Evidence 201 or consideration by the Court under the incorporation-by-reference doctrine." (RJN 9, ECF No. 62-25.) Specifically, Defendants argue that the Court should take judicial notice of Exhibits A through V and consider Exhibits A through C and F through U under the incorporation-by-reference doctrine. (*See generally id.* at 11–19.)

Lead Plaintiff counters that Defendants' RJN of Exhibits A, E through H, and J—files of the FDA, USPTO, and EMA—should be denied because "[c]ourts are consistently unwilling to allow judicial notice to be used as a tool to create and support an alternate universe of facts even where such information may be contained in public records and internet websites, or constitute governmental documents available on a government website." (RJN Opp'n 9–10, ECF No. 68 (citing *Michajlun v. Bausch & Lomb, Inc.*, No. 14-cv-1365 JM (JMA), 2015 WL 1119733, at *3 (S.D. Cal. Mar. 11, 2015)).) Similarly, documents filed with the SEC—Exhibits B, D, J, and R through U—"may not be judicially noticed for the truth of the matters stated therein." (*Id.* at 10–11.) Lead Plaintiff challenges Exhibits C, F, I, K through N, and Q on the grounds that "press releases, news articles, and analyst opinions cannot be embraced to support any factual scenario advanced by Defendants except that which is alleged in the Complaint itself." (*Id.* at 12.) Lead Plaintiff adds that "Ex. M cannot be noticed for any reason as it is not cited or referenced to or relied upon in the Complaint." (*Id.*) Lead Plaintiff objects to the Court taking judicial notice or incorporating by reference Exhibits D, E, M, and V on the grounds that "they are superfluous, irrelevant and do not meet the 'indisputability' requirements of Rule 201 with respect to the 'facts' contained therein" and, "[w]here a document is not cited or referenced in the Complaint, the incorporation by reference doctrine does not apply." (*Id.* at 12–13 (citing *Pearce v. Bank of Am. Home Loans*, No. C 09-3988 JF, 2010 WL 689798, at *3 (N.D. Cal. Feb. 23, 2010); *Witriol v. LexisNexis Grp.*, No. C05-02392 MJJ, 2006 WL

4725713, at *2–3 (N.D. Cal. Feb. 10, 2006)).) Lead Plaintiff also argues that "[a]ll of the 'factual' contentions Defendants proffer in order to contradict the well-pleaded factual allegations of the Complaint should be disregarded." (*Id.* at 14–21.)

The Court concludes that Exhibits A through C, F through L, and N through U are incorporated by reference because they are "explicitly referenced and relied on in the [Consolidated] Complaint . . . and Plaintiff[] do[es] not contest the[ir] authenticity." *See City of Royal Oak Ret. Sys. v. Juniper Networks, Inc.*, 880 F. Supp. 2d 1045, 1059 (N.D. Cal. 2012); *see also Interstate Nat. Gas Co. v. S. Cal. Gas Co.*, 209 F.2d 380, 384 (9th Cir. 1953) (considering on appeal contract referenced in amended complaint, on file with Federal Power Commission, and introduced in support of Rule 12(b)(6) motion to dismiss). Consequently, the Court may "treat such . . . document[s] as part of the complaint, and thus may assume that [their] contents are true for purposes of a motion to dismiss under Rule 12(b)(6)." *See Marder*, 450 F.3d at 448; *Ritchie*, 342 F.3d at 908. Despite Lead Plaintiff's arguments to the contrary (*see* RJN Opp'n 14–21, ECF No. 68), "[t]he district court obviously is not bound to accept the pleader's allegations as to the effect of the exhibit, but can independently examine the document and form its own conclusions as to the proper construction and meaning to be given the attached material." Charles Alan Wright et al., 5A Fed. Prac. & Proc. Civ. § 1327 (3d ed. 2016) (citing *Ott v. Home Sav. & Loan Ass'n*, 265 F.2d 643, 646–48 (9th Cir. 1958)).

Furthermore, the Court concludes that it may properly take judicial notice of Exhibits D (exhibit to Orexigen's September 11, 2014 Form 8-K), E (CHMP's December 18, 2014 report on Mysimba), and V (the WIPO Application), *see, e.g.*, *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1064 n.7 (9th Cir. 2008) (judicially noticing SEC filings); *Jasin v. Vivus, Inc.*, No. 14-CV-03263-BLF, 2016 WL 1570164, at *22 (N.D. Cal. Apr. 19, 2016) (judicially noticing CHMP reports); *Anderson v. Kimberly-Clark Corp.*, No. C12-1979RAJ, 2013 WL 9760040, at *2 (W.D. Wash. Sept. 25, 2013) (judicially noticing WIPO patent), *aff'd* 570 F. App'x 927 (Fed. Cir. 2014), although the Court cannot take notice of "the truth of the facts cited" in these Exhibits, *see Marsh*, 432 F. Supp. 2d at

1043. The Court declines, however, to judicially notice Exhibit M, the March 3, 2015 article authored by Adam Feuerstein and appearing on www.thestreet.com.

Accordingly, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' RJN (ECF No. 62-25), as outlined above.

DEFENDANTS' MTD

I. Legal Standard

Rule 12(b)(6) permits a party to raise by motion the defense that the complaint "fail[s] to state a claim upon which relief can be granted," generally referred to as a motion to dismiss. The Court evaluates whether a complaint states a cognizable legal theory and sufficient facts in light of Federal Rule of Civil Procedure 8(a), which requires a "short and plain statement of the claim showing that the pleader is entitled to relief." Although Rule 8 "does not require 'detailed factual allegations,' . . . it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). In other words, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do." *Twombly*, 550 U.S. at 555 (alteration in original). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (alteration in original) (quoting *Twombly*, 550 U.S. at 557).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly*, 550 U.S. at 570); *see also* Fed. R. Civ. P. 12(b)(6). A claim is facially plausible when the facts pled "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). That is not to say that the claim must be probable, but there must be "more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citing *Twombly*, 550 U.S. at 556). "[F]acts that are 'merely consistent with' a defendant's liability" fall short of a plausible entitlement to relief. *Id.* (quoting *Twombly*, 550 U.S. at 557). Further, the Court need not accept as true

"legal conclusions" contained in the complaint. *Id.* at 678–79 (citing *Twombly*, 550 U.S. at 555). This review requires "context-specific" analysis involving the Court's "judicial experience and common sense." *Id.* at 679. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* (quoting Fed. R. Civ. P. 8(a)(2)). The Court will grant leave to amend unless it determines that no modified contention "consistent with the challenged pleading . . . [will] cure the deficiency." *DeSoto v. Yellow Freight Sys., Inc.*, 957 F.2d 655, 658 (9th Cir. 1992) (quoting *Schriber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986)).

"Claims brought under Rule 10b-5 . . . must meet Federal Rule of Civil Procedure 9(b)'s particularity requirement that '[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.'" *In re Dura Pharm., Inc. Sec. Litig.*, 452 F. Supp. 2d 1005, 1016 (S.D. Cal. 2006) (alteration in original) (quoting Fed. R. Civ. P. 9(b)) (citing *In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006, 1014 (9th Cir. 2005), *cert. denied* 546 U.S. 1172 (2006); *Yourish v. Cal. Amplifier*, 191 F.3d 983, 993 (9th Cir. 1999)). "In addition, in 1995, Congress enacted the Private Securities Litigation Record Act of 1995 (PSLRA) and altered the pleading requirements in private securities fraud litigation by requiring a complaint plead with particularity both falsity and scienter." *Id.* at 1016–17 (quoting *Daou Sys.*, 411 F.3d at 1014) (internal quotation marks omitted).

II. Analysis

Lead Plaintiff alleges three causes of action: (1) violations of § 10(b) of the Exchange Act and Rule 10b-5(b) against all Defendants, (2) violations of § 10(b) of the Exchange Act and Rules 10b-5(a) & (c) against all Defendants, and (3) violations of § 20(a) of the Exchange Act against the Insider Defendants. (CC ¶¶ 142–55, ECF No. 55.) Defendants move to dismiss Lead Plaintiff's CC for failure to state a claim. (MTD 2, ECF No. 62.) The Court addresses each of Lead Plaintiff's causes of action in turn.

/ / /

A. First Cause of Action: Violations of § 10(b) of the Exchange Act and Rule 10b-5(b) Against Defendants

"Section 10(b) of the Securities Exchange Act of 1934 forbids (1) the 'use or employ[ment] . . . of any . . . deceptive device,' (2) 'in connection with the purchase or sale of any security,' and (3) 'in contravention of' Securities and Exchange Commission 'rules and regulations.'" *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341 (2005) (quoting 15 U.S.C. § 78j(b)). "Commission Rule 10b-5 forbids, among other things, the making of any 'untrue statement of a material fact' or the omission of any material fact 'necessary in order to make the statements made . . . not misleading.'" *Id.* (quoting 17 CFR § 240.10b-5 (2004)). "The basic elements of a Rule 10b-5 claim, therefore, are: (1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss." *Daou Sys.*, 411 F.3d at 1014 (citing *Dura Pharms.*, 544 U.S. at 341–42). Because the Court concludes that Lead Plaintiff has failed to plead a material misrepresentation or omission of fact, the Court need not address the remaining elements of Plaintiff's Rule 10b-5(b) cause of action.

A statement or omission is misleading "if it would give a reasonable investor the 'impression of a state of affairs that differs in a material way from the one that actually exists.'" *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2008) (quoting *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)). "[A]n omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important." *Basic Inc. v. Levinson*, 485 U.S. 224, 231 (1988) (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976). "[T]here must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Id.* at 231–32 (quoting *TSC Indus.*, 426 U.S. at 449). "[I]t bears emphasis that § 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011). "Disclosure is required under these provisions only when necessary 'to make . . . statements made, in

light of the circumstances under which they were made, not misleading.'" *Id.* (quoting 17 C.F.R. § 240.10b-5(b)).

1. Orexigen's Current Report on Form 8-K (March 3, 2015)

Lead Plaintiff alleges that Defendant Orexigen's March 3, 2015 Form 8-K, in which it announced the issuance of the '371 Patent and the 25% interim Light Study data, was "materially false and misleading" for a number of reasons, including:

> (i) the 25% study results Defendants improperly released on March 3, 2015 showing that Contrave reduced the risk of heart attacks and cardiovascular death were "unreliable," "likely false," and "misleading;" (ii) Orexigen violated the FDA Agreement forbidding the Company from releasing Light Study interim results; (iii) Orexigen knew, no later than July 2, 2014, that Defendant Klassen had included specific interim Light Study data in the 2014 Patent Application; (iv) Orexigen had made a request with the USPTO in January 2015 to have the patent publicly disseminated; (v) Orexigen faced potential fines, civil penalties, and the possible removal of Contrave from the market by the FDA; and (vi) as a result of the above, the Company's Class Period filings with the SEC were materially false and misleading at all relevant times.

(CC ¶ 92, ECF No. 55.)

Defendants argue that, "to this day, no one has identified any false information disclosed in the graph or in any other aspect of the 25% analysis." (MTD Mem. 18, ECF No. 62-1.) Moreover, "the 8-K could not have been clearer that the data was 'interim' and that a 'larger number of MACE are required to precisely determine the effect of Contrave on CV outcomes.'" (*Id.* (quoting CC ¶ 87, ECF No. 55).) Consequently, "[t]here simply was no fraud." (*Id.* at 19.) Lead Plaintiff counters that "the Company misrepresented that Contrave reduced cardiovascular events by 41% compared with a placebo without disclosing that the FDA had previously told defendants Klassen and Narachi that the 25% data was 'far too unreliable to conclude ***anything***.'" (MTD Opp'n 18, ECF No. 67 (emphasis in original) (citing CC ¶¶ 18, 47, 96, 126, ECF No. 55).) "While Orexigen may have accurately reported what the 25% interim data ***appeared*** to show, . . . Defendants do not credibly dispute that they exaggerated the 25% data's statistical significance and failed

to disclose that it was unreliable." (*Id.* (emphasis in original).) "Moreover, nowhere in the 8-K did Orexigen disclose that the Company had signed the FDA Agreement prohibiting it from releasing the 25% data." (*Id.*) Had investors known this information, they "could have stayed on the sidelines until the statistically relevant 50% data became available." (*Id.* at 19.)

The Court concludes that there were no material misrepresentations or omissions of fact in Defendant Orexigen's March 3, 2015 8-K. First, although dissemination of the 25% interim results further violated Defendant Orexigen's data access plan, Defendant Orexigen nowhere claimed that it had the FDA's approval to publish the data. Consequently, there was no affirmative duty to disclose the violation of the data access plan. *See Matrixx Initiatives*, 563 U.S. at 44 ("Disclosure is required under these provisions only when necessary 'to make . . . statements made, in light of the circumstances under which they were made, not misleading.'") (quoting 17 C.F.R. § 240.10b-5(b)).

Moreover, and more importantly, Defendants did not misrepresent the 25% interim data. The 8-K made clear that "[t]he 371 Patent . . . incorporate[s] data from a pre-planned interim analysis of the large, randomized, placebo-controlled, cardiovascular . . . outcomes trial of Contrave®" and that "[t]he 371 Patent . . . contain[s] claims related to a positive effect of Contrave on CV outcomes." (CC ¶ 87, ECF No. 55.) The 8-K further disclosed:

> This analysis was conducted based on 94 observed and adjudicated major adverse cardiovascular events . . . , which was approximately 25% of the planned MACE for the Light Study . . . . The 25% Interim Analysis was prospectively designed to enable an early and preliminary assessment of safety to support regulatory approval. A larger number of MACE are required to precisely determine the effect of Contrave on CV outcomes.

(*Id.*) Defendants themselves did not claim that the results were statistically significant, even if analysts later jumped to that conclusion. (*See, e.g.*, *id.* at ¶ 91 ("On March 3, 2015 Leerink analyst Paul Matteis . . . not[ed] that . . . '. . . The data this morning show a statistically significant Contrave benefit . . . .'") (emphasis omitted).) Rather, Defendants twice cautioned that "[t]he 25% Interim Analysis was prospectively designed to enable an

early and preliminary assessment of safety to support regulatory approval. A larger number of MACE are required to precisely determine the effect of Contrave on CV outcomes." (*See* RJN Ex. J at 3, 5, ECF No. 62-12.)

Consequently, Defendants are correct that "the 8-K could not have been clearer that the data was 'interim' and that a 'larger number of MACE are required to precisely determine the effect of Contrave on CV outcomes.'" (*See* MTD Mem. 18, ECF No. 62-1 (quoting CC ¶ 87, ECF No. 55).) Accordingly, the Court **DISMISSES WITH PREJUDICE** Plaintiff's first cause of action to the extent it is predicated upon material misstatements or omissions of fact in Defendant Orexigen's March 3, 2015 8-K.

2. Orexigen's Press Release (March 3, 2015)

On March 3, 2015, Defendant Orexigen issued a press release noting that "[t]his morning the USPTO published the ['371 P]atent and supporting documentation." (CC ¶ 94, ECF No. 55.) Lead Plaintiff asserts that Defendant Orexigen's "representation that the USPTO had independently published the patent without the Company's input was highly misleading" because Defendant Orexigen "failed to disclose that the USPTO only published what Orexigen itself needlessly put into the 2014 Patent Application." (*Id.* at ¶ 95.) Lead Plaintiff further alleges that "Defendants also failed to disclose that [Defendant Orexigen] had rescinded its earlier request that the 2014 Patent Application remain unpublished. In truth, [Defendant Orexigen] even paid the USPTO an extra fee to expedite publication of the 25% interim Light Study data." (*Id.*)

Defendants argue that these allegations are "based on a misunderstanding of the patent process." (MTD Mem. 18–19, ECF No. 62-1.) Defendants explain that, "[i]n general, patent applications must be 'kept in confidence' by the PTO for at least 18 months, at which time the application is published." (*Id.* at 10–11 (citing 35 U.S.C. §§ 122(a), (b)(1)(A)).) "An applicant may request that an application remain unpublished even after 18 months *if* the invention is not subject to a patent application in another country that requires publication within 18 months." (*Id.* at 11 (emphasis in original) (citing 35 U.S.C. § 122(b)(2)(B)(i)).) "Orexigen . . . sought prioritized *examination* of the Application, but

did not request (much less pay for) expedited *publication*." (*Id.* (emphasis in original) (citing RJN Ex. H at 3, 9, ECF No. 62-10).) "Because the [WIPO A]pplication would also be published 18 months after its priority date, Orexigen was obligated by law to rescind its request that the Application not be published." (*Id.* (footnote omitted) (citing 35 U.S.C. § 122(b)(2)(B)(iii)).) "Orexigen did so on January 5, 2014, and the PTO set the Application to be published on June 11, 2015." (*Id.* (citing RJN Ex. H at 20, ECF No. 62-10).) When the USPTO published the '371 Patent of March 3, 2015, "the June 2015 publication date for the Application no longer mattered." (*Id.*)

The Court agrees with Defendants that Lead Plaintiff's allegations are based on a misunderstanding of the patent process. Defendants were required to notify the USPTO of the filing of the WIPO Application within forty-five days or the '810 Application would be "regarded as abandoned." 35 U.S.C. § 122(b)(2)(B)(iii). Although it is true that Defendants requested prioritized examination pursuant to 37 C.F.R. § 1.102(e) (*see* RJN Ex. H at 9–10, ECF No. 62-10), it is the USPTO that ultimately determines the timetable for issuance of the patent and publication of the application. Consequently, the USPTO did not publish the '371 Patent "with[] the Company's input." (CC ¶ 95, ECF No. 55.)

Lead Plaintiff's allegation that Defendant Orexigen "needlessly put [the 25% interim data] into the ['810] Application" is equally misguided. (*See id.* at ¶ 95.) Lead Plaintiff acknowledges that the '810 Application disclosed that "***[s]urprisingly***, rather than increasing the occurrence of MACE in this high risk patient population, the results indicate that treatment with [Contrave] ***decreases*** the occurrence of MACE in overweight and obese subjects with cardiovascular risk factors." (*Id.* at ¶ 62 (emphasis in original).) The Federal Circuit has explained that, under such circumstances, supporting data may be required to demonstrate enablement during patent prosecution:

> where there is "no indication that one skilled in [the] art would accept without question statements [as to the effects of the claimed drug products] and no evidence has been presented to demonstrate that the claimed products do have those effects," an applicant has failed to demonstrate sufficient utility and therefore cannot establish enablement [pursuant to 35 U.S.C. § 112].

Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1323 (Fed. Cir. 2005) (first and second alterations in original) (quoting *Application of Novak*, 306 F.2d 924, 928 (C.C.P.A. 1962)). In light of these authorities and the parties' recognition that the '810 Patent explicitly conceded the "[s]urprising[]" nature of the 25% interim results, Lead Plaintiff's allegations that Defendant Orexigen "needlessly put [the 25% interim data] into the ['810] Application" (*see* CC ¶ 95, ECF No. 55) is not based on a "cognizable legal theory" and must be dismissed. *See, e.g.*, *Taylor v. Yee*, 780 F.3d 928, 935 (9th Cir. 2015) ("Dismissal [under Rule 12(b)(6)] is proper only where there is no cognizable legal theory or an absence of sufficient facts alleged to support a cognizable legal theory.") (quoting *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001)), *cert. denied* 136 S. Ct. 929 (2016).

Accordingly, the Court **DISMISSES WITH PREJUDICE** Plaintiff's first cause of action to the extent it is predicated upon material misstatements or omissions of fact appearing in Defendant Orexigen's March 3, 2015 press release.

3. Orexigen's Current Report on Form 8-K (May 8, 2015)

On May 8, 2015, Defendant Orexigen filed an 8-K announcing that "[t]he clinical trial program also includes a double-blind, placebo-controlled cardiovascular outcomes trial known as the Light Study." (CC ¶ 100, ECF No. 55 (emphasis omitted).) Lead Plaintiff alleges that "the Form 8-K failed to disclose that the Light Study had been terminated weeks earlier on March 26, 2015 and that the 50% interim data demonstrated that the Company's prior representations about Contrave's purported cardiovascular benefit were false." (*Id.* at ¶ 101.) Consequently, the statements and material omissions in the 8-K "were materially false and misleading and/or failed to disclose that: . . . all of the Defendants knew or were deliberately reckless in not knowing no later than March 26, 2015 that the Light Study had been terminated and that the 50% interim data showed no heart benefit." (*Id.* at ¶ 102.)

With respect to Lead Plaintiff's allegations concerning the termination of the Light Study, Defendants argue that "the CC does not plead facts supporting its allegation that the ESC vote in March 2015 terminated the Light Study at that time" and, "because trial

sponsors, not ESCs, decide whether and when to terminate clinical trials, any ESC vote to halt a trial is a *recommendation*, not a termination." (MTD Mem. 20–21, ECF No. 62-1.) Moreover, "[i]nvestors were aware that Orexigen and Takeda had been evaluating the fate of the Light Study for some time" and, "given that Orexigen and Takeda publicly disclosed just four days later that they had accepted the recommendation of the ESC and terminated the trial . . . , it makes no sense to allege that Defendants hid this fact." (*Id.* at 21 (citation omitted).) With regard to the 50% data, Defendants argue that "[o]n May 8, Orexigen said *nothing* about the CV effect demonstrated by the 50% data." (*Id.*) "Further, Orexigen had no independent duty to disclose the 50% results on May 8, even if it knew what the analysis revealed." (*Id.* at 22 (citing *Matrixx Initiatives*, 563 U.S. at 44; *WPP Lux. Gamma Three Sarl v. Spot Runner, Inc.*, 655 F.3d 1039, 1048 (9th Cir. 2011)).) "Before May 8, Orexigen had only disclosed the 25% data, which had not changed. Orexigen had no duty to update this accurate statement of historical fact." (*Id.* (citing *In re Foxhollow Techs., Inc. Sec. Litig.*, 359 Fed. App'x 802, 804–05 (9th Cir. 2009)).)

Lead Plaintiff counters that "[o]n March 26, 2015, defendants were specifically told that the Light Study had been terminated and that the 25% data they touted on March 3, 2015 had been deemed invalid at the 50% mark." (MTD Opp'n 20, ECF No. 67.) Consequently, "even if the ESC's vote could be denigrated as [a recommendation], defendants ***still*** failed to disclose that the ESC had unanimously voted to end the Light Study due to defendants' improper disclosure of 25% interim data." (*Id.* at 23 (emphasis in original).) Moreover, "[Defendants'] failure to disclose the truth they then knew about the 50% data . . . is black-letter securities fraud." (*Id.* at 21 (citing *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 987 (9th Cir. 2008); *Reese v. Malone*, 747 F.3d 557, 574 (9th Cir. 2014)).) In short, "defendants made public statements while in the possession of information that contradicted those statements." (*Id.* at 22 (citing *Nursing Home Pension Fund, Local 144 v. Oracle Corp.*, 380 F.3d 1226, 1230 (9th Cir. 2004)).)

The Court concludes that Lead Plaintiff has failed sufficiently to allege any material misstatements or omissions of fact appearing in Defendant Orexigen's May 8, 2015 Form

8-K. Regarding the termination of the Light Study, despite Lead Plaintiff's conclusory allegations that the Light Study had terminated on March 26, 2015 (*see, e.g.*, CC ¶ 101, ECF No. 55), Lead Plaintiff's other allegations and the evidence the Court may properly consider instead compel the conclusion that the ESC's vote was merely a recommendation (*see, e.g.*, *id.* at ¶ 127 ("The executive committee voted unanimously to recommend that the trial be stopped . . . ."); *see also* RJN Ex. Q at 2, ECF No. 62-19 ("Takeda . . . and Orexigen . . . have accepted the recommendation of the [ESC] . . . for early termination of the Light Study . . . .")), as Defendants argue (*see* MTD Mem. 20, ECF No. 62-1). Neither of the May 12, 2015 press releases indicates that the study was terminated prior to that date. (*See* CC ¶ 126, ECF No. 55 ("Following premature disclosure of interim results, the 9,000-patient Light Trial . . . has been halted by the trial's executive steering committee . . . .") (emphasis omitted); *see also* RJN Ex. Q at 2, ECF No. 62-19.) Moreover, Defendant Orexigen had already reported to the press that it was recommending "that LIGHT be stopped as it is not a post-marketing requirement and has less utility over time as more and more cardiovascular events happen off therapy." (*See* RJN Ex. P at 2, ECF No. 62-18.) In light of the evidence contradicting Lead Plaintiff's conclusory allegations that the Light Study terminated prior to May 12, 2015 and Defendant Orexigen's prior disclosure that it was recommending termination of the Light Study, the Court concludes that Defendant Orexigen's May 8, 2015 8-K did not contain material omissions of fact concerning the termination of the Light Study.

Additionally, the May 8, 2015 8-K did not contain material misstatements or omissions of fact regarding the 50% interim data. The May 8, 2015 8-K did not mention the 50% interim results, and so did not contain any material misstatements. Moreover, the failure of the 8-K to include the 50% interim data did not constitute an "omi[ssion] to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading," *see United States v. Laurienti*, 611 F.3d 530, 539 (9th Cir. 2010) (quoting 17 C.F.R. § 240.10b-5(b)), because the statements made about the interim 25% results on March 3, 2015 were not rendered

misleading. The interim 25% results still showed "a positive effect of Contrave on CV outcomes" and it was still true that "[a] larger number of MACE are required to precisely determine the effect of Contrave on CV outcomes." (CC ¶ 87, ECF No. 55.) For the same reason, Defendant Orexigen was also under no affirmative duty to disclose the 50% interim results. *See Matrixx Initiatives*, 563 U.S. at 44. Rather, as Defendant Orexigen later explained on its earnings conference call that same day, Defendant Orexigen was unable to publicize the results of the 50% interim data pursuant to the data access plan. (*See, e.g.*, CC ¶¶ 109–10, ECF No. 55.) Lead Plaintiff's allegations leave Lead Plaintiff in the awkward position of faulting Defendant Orexigen for disclosing the 25% interim results in contravention of the data access plan, but then criticizing Defendant Orexigen for *not* doing the same with the 50% interim data.

Although the Court harbors doubts that Lead Plaintiff can cure the deficiencies outlined above, in an abundance of caution, the Court **DISMISSES WITHOUT PREJUDICE** Lead Plaintiff's first cause of action to the extent it is predicated upon material misstatements or omissions of fact appearing in Defendant Orexigen's May 8, 2015 8-K. *See, e.g.*, *Hague v. Wells Fargo Bank, N.A.*, No. C11-02366 TEH, 2011 WL 3360026, at *4 (N.D. Cal. Aug. 2, 2011).

4. Orexigen's Quarterly Report on Form 10-Q (May 8, 2015)

On May 8, 2015, Defendant Orexigen also filed a 10-Q, which "failed to disclose that the Light Study had been terminated and that the 50% interim data demonstrate that the 25% data Defendants had released on March 3, 2015 was false." (CC ¶ 103, ECF No. 55.) Specifically, the 10-Q noted that "additional analysis of the interim results or new data from the continuing Light Study, including safety-related data, and the additional cardiovascular outcomes trial, may produce negative or inconclusive results, or may be inconsistent with the conclusion that the interim analysis was successful." (*Id.* at ¶ 104 (emphasis omitted).)

The parties' arguments for and against dismissal of the May 8, 2015 10-Q allegations are largely similar to those for and against dismissal of the May 8, 2015 8-K allegations.

(*See* MTD Mem. 19–21, ECF No. 62-1 (arguing for dismissal of "challenge[d] statements made by the Company on May 8, 2015"); MTD Opp'n 20–23, ECF No. 67 (arguing that "Defendants' materially false and misleading May 8, 2015 statements and omissions are actionable") (emphasis omitted).) Accordingly, for the reasons discussed above, *see supra* Part II.A.3, the Court **DISMISSES WITHOUT PREJUDICE** Lead Plaintiff's first cause of action to the extent it is predicated upon material misstatements or omissions of fact appearing in Defendant Orexigen's May 8, 2015 10-Q.

5. Orexigen's 1Q 2015 Earnings Conference Call (May 8, 2015)

Lead Plaintiff alleges that "[o]n May 8, 2015, the Company hosted its 1Q 2015 earnings conference call for analysts and investors." (CC ¶ 107, ECF No. 55.) During that call, "Defendant Klassen knowingly and/or with deliberate indifference represented that the 'Light Study is continuing and we are continuing to engage both Orexigen and Takeda with the FDA and with ESC and DMC regarding ultimately the status of the study, but it's an ongoing entity as of right now." (*Id.* at ¶ 108 (emphasis omitted).) Defendant Klassen also "failed to disclose that the 50% interim data he had seen weeks earlier showed that the 25% data was false" when he reported that "[w]e have passed the 50% time point and as we've stated before, those results are viewed by the Data Monitoring Committee and it wasn't a planned look by the sponsors, like the 25% was. The 25% was special because it was for regulatory purposes and so we have had 50% time point." (*Id.* at ¶ 109 (alteration in original).) Defendant Narachi added:

> [t]he results from the 50% analysis, I think the way to think about it is, those only come out in the context of wrapping up the trial or as a final analysis. So, if the decision is made to terminate the trial early and focus resources on the next CVOT, which is what we have been advocating, then I think results would come out sooner . . . .

(*Id.* at ¶ 110 (emphasis omitted).) Defendant Narachi also noted that "I think that [the fate of the Light Study] would be something we disclose. . . . [I]f there was a decision to terminate the trial and move on and focus resources on the new CVOT, that would be a disclosure that we would make." (*Id.* at 111 (emphasis omitted).)

Again, the parties' arguments for and against dismissal are largely repetitive of those made above. (*See* MTD Mem. 19–21, ECF No. 62-1; MTD Opp'n 20–23, ECF No. 67.) Accordingly, for the reasons discussed above, *see supra* Parts II.A.3, 4, the Court **DISMISSES WITHOUT PREJUDICE** Lead Plaintiff's first cause of action to the extent it is predicated upon material misstatements or omissions of fact made in Defendant Orexigen's May 8, 2015 earnings conference call.

B. Second Cause of Action: Violations of § 10(b) of the Exchange Act and Rules 10b-5(a) & (c) Against Defendants

"Under Rule 10b-5(a) or (c), a defendant who uses a 'device, scheme, or artifice to defraud,' or who engages in 'any act, practice, or course of business which operates or would operate as a fraud or deceit,' may be liable for securities fraud." *WPP Lux.*, 655 F.3d at 1057 (quoting 17 C.F.R. § 240.10b-5(a), (c)) (citing *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta*, 552 U.S. 148, 158 (2008)), *cert. denied* 132 S. Ct. 2713 (2012). This is often referred to as "scheme liability." *See Stoneridge*, 552 U.S. at 149. "A defendant may only be liable as part of a fraudulent scheme based upon misrepresentations and omissions under Rules 10b-5(a) or (c) when the scheme also encompasses conduct beyond those misrepresentations or omissions." *WPP Lux.*, 655 F.3d at 1057–58 (citing *SEC v. Lucent Techs., Inc.*, 610 F. Supp. 2d 342, 359 (D.N.J. 2009); *SEC v. Patel*, No. 07-cv-39-SM, 2009 WL 3151143, at *6–7 (D.N.H. Sept. 30, 2009); *In re Nat'l Century Fin. Enters., Inc. Inv. Litig.*, No. 2:03-MD-1565, 2006 WL 469468, at *21 (S.D. Ohio Feb. 27, 2006); *In re Alstom SA Sec. Litig.*, 406 F. Supp. 2d 433, 475 (S.D.N.Y. 2005)). "Manipulative conduct . . . is actionable under Rule 10b-5(a) or (c) and includes activities designed to affect the price of a security artificially by simulating market activity that does not reflect genuine investor demand." *Desai v. Deutsche Bank Sec. Ltd.*, 573 F.3d 931, 940-41 (9th Cir. 2009) (citing *Santa Fe Indus., Inc. v. Green*, 430 U.S. 462, 476–77 (1977); *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 199 (1976) ("[Manipulation] connotes intentional or willful conduct designed to deceive or defraud investors by controlling or artificially affecting the price of securities.")). "To state a primary liability claim under Rules 10b-

5(a) or (c), a plaintiff must allege a device, scheme or artifice to defraud, or an act, practice or course of business which would operate as a fraud, in addition to alleging the standard elements of a § 10(b) and Rule 10b-5 violation." *N.Y. City Emps.' Ret. Sys. v. Berry*, 616 F. Supp. 2d 987, 996 (N.D. Cal. 2009) (citing *Stoneridge*, 552 U.S. at 158).

Defendants argue that Lead Plaintiff's "scheme claim must be dismissed because it is nothing more than a repackaging of the Rule 10b-5(b) claims discussed above." (MTD Mem. 27, ECF No. 62-1 (citing CC ¶¶ 142–52, ECF No. 55).) Moreover, "even if the CC's farfetched 'patent scheme' theory was actionable under the securities laws, the judicially-noticeable documents make clear that no such scheme existed (or makes any sense)" because Defendant "Orexigen did not request non-publication of the patent Application to keep the FDA in the dark," Defendant "Orexigen's rescinding of [the non-publication] request [did not] have anything to do with the timing of the '371 [P]atent issuance on March 3, 2015," "[a]nd finally, Orexigen had no need to engage in a patent charade to get the 25% data to European regulators; they already had it." (*Id.* at 28.) Defendant also argues that Lead Plaintiff cannot show reliance because "[Defendant Orexigen]'s prosecution of the patent . . . had no effect on its stock price." (MTD Reply 14, ECF No. 69.)

Lead Plaintiff counters that "Plaintiff alleges that Orexigen had no credible reason to even file its formal patent application on July 2, 2014 because its intellectual property rights were ***already*** protected by the Company's previously-filed December 2013 provisional patent application," meaning that "defendants engaged in a scheme to use a patent application that included statistically insignificant data to publicize the 25% interim Light Study data." (MTD Opp'n 27, ECF No. 67 (emphasis in original).) Moreover, "Plaintiff alleges that Orexigen then requested prioritized examination of its formal patent application" to "advance[] the publication date well in advance of the eighteen-month nonpublication period it now points to," an "action[] . . . designed to release the 25% data, not to protect [Defendant Orexigen's] intellectual property." (*Id.* at 28–29.)

The crux of Lead Plaintiff's scheme liability cause of action is that "Defendants Narachi and Klassen engaged in an undisclosed reckless scheme to leak the positive 25%

interim data they knew they were prohibited from revealing *via* the ['810] Application." (CC ¶ 61, ECF No. 55; *see also id.* at ¶ 12; MTD Opp'n 27, ECF No. 67.) Lead Plaintiff's first cause of action, however, is also premised upon statements that "were materially false and misleading" because:

> Orexigen violated the [data access plan] forbidding the Company from releasing Light Study interim results; . . . Orexigen knew, no later than July 2, 2014, that Defendant Klassen had included specific interim Light Study data in the ['810] Application; [and] Orexigen had made a request with the USPTO in January 2015 to have the patent publicly disseminated . . . .

(CC ¶ 92, ECF No. 55.) Both Lead Plaintiff's Rule 10b-5(b) and scheme liability causes of action hinge upon the wrongful dissemination of the 25% interim data through the filing of the '810 Application. Although it is a close question, the Court is inclined to conclude that Lead Plaintiff's scheme liability cause of action does not allege conduct beyond that underlying the alleged misrepresentations and omissions of fact. Consequently, "the scheme [does not] encompass[] conduct beyond those misrepresentations or omissions" and must be dismissed. *See WPP Lux.*, 655 F.3d at 1057.

Even if the Court were to find that Lead Plaintiff's scheme liability cause of action alleged conduct beyond the misrepresentations and omissions, however, "there is no indication that Defendants' action . . . would constitute a deceptive act." *See Abbate v. Wells Fargo Bank, N.A.*, No. CV 10-6561 DOC RNBX, 2011 WL 9698215, at *3 (C.D. Cal. Nov. 17, 2011); *see also Veltex Corp. v. Matin*, No. CV 10-1746 ABC PJWX, 2010 WL 3834045, at *6 n.9 (C.D. Cal. Sept. 27, 2010) (dismissing scheme liability claim where "[p]laintiff has failed to allege with specificity an actionable deceptive act purportedly engaged in by [defendant]"). In the Ninth Circuit, "engaging in a transaction, the principal purpose and effect of which is to create the false appearance of fact, constitutes a 'deceptive act.'" *Simpson v. AOL Time Warner Inc.*, 452 F.3d 1040, 1048 (9th Cir. 2006), *vacated on other grounds*, 552 U.S. 1162; 519 F.3d 1041 (9th Cir. 2008); *Burnett v. Rowzee*, No. SA CV 07-641DOCANX, 2007 WL 4754539, at *5 (C.D. Cal. Oct. 18, 2007) ("[T]he defendant's act must, standing alone, be manipulative or deceptive and must further the

fraudulent scheme."). The Court agrees with Defendants that the filing of the '810 Application was "not inherently deceptive or manipulative." (*See* MTD Reply 13–14, ECF No. 69.)

As the Court explained previously, *see supra* Part II.A.2, Lead Plaintiff's allegations concerning the patent scheme are based upon a misunderstanding of the patent process. Defendants filed a provisional patent application on December 6, 2013. (*See* RJN Ex. G at 2, ECF No. 62-9.) They were required to file a non-provisional patent application claiming the benefit of the provisional application within twelve months. 35 U.S.C. § 111(b)(5). Patent applications are not published for eighteen months "from the earliest filing date for which a benefit is sought," 35 U.S.C. § 122(b)(1)(A), meaning that Defendants' provisional patent application would generally have been published in early June 2014. As Lead Plaintiff acknowledges, however, Defendants originally requested that the USPTO *not* publish the '810 Application at that time. (CC ¶ 61, ECF No. 55; *see also* RJN Ex. H at 3, ECF No. 62-10.) Defendants only rescinded this request on January 5, 2015 (RJN Ex. H at 20–21, ECF No. 62-10), within forty-five days of filing the WIPO Application on December 4, 2014 (RJN Ex. V at 2, ECF No. 62-24), as required under 35 U.S.C. § 122(b)(2)(B)(iii). Although the USPTO projected a new publication date for the '810 Application of June 11, 2015 (RJN Ex. H at 23, ECF No. 62-10), the USPTO ultimately issued the '371 Patent before that date on March 3, 2015 (RJN Ex. G, ECF No. 62-9).

The evidence also contradicts Lead Plaintiff's allegations that the patent scheme was intended to publicize the 25% interim results to European regulators by March 2015, as Defendants had already provided that data to CHMP by December 18, 2014. (*See* RJN Ex. E at 11–12, ECF No. 62-7 ("The Application has submitted the first interim report of the NB-CVOT study. . . ."); RJN Ex. F at 1, ECF No. 62-8 ("Interim results from an ongoing cardiovascular outcome trial were reassuring in terms of risk of serious cardiovascular disease related to treatment with Mysimba.").) Consequently, while it is true that Defendants violated their own data access plan and disregarded the FDA's "significant

concerns" regarding breaches of that confidentiality (*see, e.g.*, CC ¶¶ 10–11, 59–60, ECF No. 55), Lead Plaintiff's allegations that the primary purpose and effect of the filings of the '810 Application was to wrongfully publicize the 25% interim results are not borne out by the evidence the Court may properly consider on Defendants' MTD. Consequently, Lead Plaintiff fails plausibly to plead the requisite deceptive act. *See Simpson*, 452 F.3d at 1048. Accordingly, the Court **DISMISSES WITHOUT PREJUDICE** Plaintiff's second cause of action.[4]

C. Third Cause of Action: Violations of § 20(a) of the Exchange Act Against the Insider Defendants

"Section 20(a) of the Act makes certain 'controlling' individuals also liable for violations of section 10(b) and its underlying regulations." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009), *as amended* (Feb. 10, 2009). Specifically, Section 20(a) provides:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable (including to the Commission in any action brought under paragraph (1) or (3) of section 78u(d) of this title), unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a). "Thus, a defendant employee of a corporation who has violated the securities laws will be jointly and severally liable to the plaintiff, as long as the plaintiff demonstrates 'a primary violation of federal securities law' and that 'the defendant

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[4] The Court **DISMISSES WITH PREJUDICE**, however, Lead Plaintiff's second cause of action against Defendant Hagan on the ground of abandonment. Although the CC alleges that *all* defendants violated § 10(b) and Rules 10b-5(a) and (c) (CC ¶¶ 147–52, ECF No. 55), Lead Plaintiff's Opposition argues only that "Plaintiff adequately pleads scheme liability against Defendants Orexigen, Narachi and Klassen" (MTD Opp'n 27, ECF No. 67). Lead Plaintiff has therefore abandoned his second cause of action against Defendant Hagan, which the Court may dismiss with prejudice. *See, e.g.*, *Qureshi v. Countrywide Home Loans, Inc.*, No. 09–4198, 2010 WL 841669, at *6 n.2 (N.D. Cal. Mar. 10, 2010) (citing *See Jenkins v. Cnty. of Riverside*, 398 F.3d 1093, 1095 n.4 (9th Cir. 2005)); *In re TFT-LCD (Flat Panel) Antitrust Litig.*, 586 F. Supp. 2d 1109, 1131 (N.D. Cal. 2008).

exercised actual power or control over the primary violator.'" *Zucco Partners*, 552 F.3d at 990 (quoting *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 945 (9th Cir. 2003)) (citing *Paracor Fin., Inc. v. Gen. Elec. Capital Corp.*, 96 F.3d 1151, 1161 (9th Cir. 1996)). "Section 20(a) claims may be dismissed summarily . . . if a plaintiff fails to adequately plead a primary violation of section 10(b)." *Id.* (citing *In re VeriFone Sec. Litig.*, 11 F.3d 865, 872 (9th Cir. 1993); *In re Metawave Commc'ns Corp. Sec. Litig.*, 298 F. Supp. 2d 1056, 1087 (W.D. Wash. 2003)).

Because the Court has dismissed Lead Plaintiff's causes of action predicated upon violations of Section 10(b), *see supra* Parts II.A, B, the Court **GRANTS** Defendants' MTD and **DISMISSES WITHOUT PREJUDICE** Lead Plaintiff's third cause of action against the Individual Defendants for violations of Section 20(a).

CONCLUSION

In light of the foregoing, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' RJN (ECF No. 62-25), **GRANTS** Defendants' MTD (ECF No. 62), and **DISMISSES** Lead Plaintiff's CC (ECF No. 55). Specifically, the Court **DISMISSES WITH PREJUDICE** Lead Plaintiff's first cause of action for violations of Section 10(b) and Rule 10b-5(b) to the extent it is predicated upon material misstatements or omissions of fact made in Defendants' March 3, 2015 statements and second cause of action for violations of Section 10(b) and Rules 10b-5(a) and (c) against Defendant Hagan. The Court **DISMISSES WITHOUT PREJUDICE** Lead Plaintiff's remaining causes of action. Lead Plaintiff **MAY FILE** an amended consolidated complaint (ACC) within thirty (30) days of the date on which this Order is electronically docketed. *Failure to file an ACC by this date may result in dismissal of this action with prejudice*.

IT IS SO ORDERED.

Dated: May 19, 2016

Janis L. Sammartino
Hon. Janis L. Sammartino
United States District Judge